Remarks

Claims 1-31 are pending in this application. Claims 1 and 12-13 have been amended, and no claims have been added or canceled.

Applicants wish to thank the Examiner for extending the courtesy of a telephone interview on July 15, 2003. Reconsideration of this application is respectfully requested in light of the above amendments and the following remarks.

Allowed Claims

Applicants appreciate the Examiner's indication that claims 24-31 have been allowed.

Drawings

Applicants submit herewith a replacement drawing sheet which includes changes to FIG. 7. In particular, Applicants have amended claim 7 to more clearly show the inlet tube received over the connector proximal end. Support for this amendment can be found at p. 8, lines 27-29 of the specification. No new matter has been entered.

Rejection of Claim 1-23 Under 35 U.S.C. § 112

Claims 1-23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner cites a lack of antecedent basis for the term "the body" in claims 1, 12, and 13, as well as stating that it is unclear what is meant by the term "an interference fit." Applicants appreciate the Examiner's careful review of the claims, and have amended claims 1, 12, and 13 to instead recite that the breathing tube or inlet tube remains external to "the patient" for which antecedent basis exists. In addition, Applicants have amended claim 1 to remove the recitation of "an interference fit." These amendments are solely to address issues under 35 U.S.C. § 112 and add no new element. During the aforementioned telephone interview, the Examiner indicated that these claim amendments should be sufficient to overcome the rejections under 35 U.S.C. § 112. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-3, 6, and 10
Under 35 U.S.C. § 102(e) Over Clayton

Claims 1-3, 6, and 10 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,197,044 issued to Clayton ("Clayton"). In response, Applicants have amended claim 1 to more particularly point out and distinctly claim the subject matter of the invention.

Specifically, claim 1 now recites that "the inlet opening has an outer diameter of approximately 15 mm for receiving a standard breathing tube on an outer surface of the inlet opening, the breathing tube remaining external to the patient" (*see* p. 4, lines 10-12; p. 7, lines 23-30; p. 8, lines 18-31). Applicants assert that Clayton does not disclose or suggest this combination. The Examiner admits that Clayton fails to teach an inlet opening having an outer diameter of approximately 15 mm (Office Action, Page 7, ¶15), and the Examiner indicated during the July 15, 2003 telephone interview that this amendment to claim 1 should be sufficient to overcome the rejection under 35 U.S.C. § 102(e). Accordingly, Applicants believe that claim 1 is patentably distinguishable over Clayton, and respectfully request reconsideration and withdrawal of the rejection of this claim and its corresponding dependent claims under 35 U.S.C. § 102(e).

Rejection of Claims 4-5, 7, 9, and 11
Under 35 U.S.C. § 103(a) Over Clayton

Claims 4-5, 7, 9, and 11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton. Claims 4-5, 7, 9, and 11 depend from and contain all the limitations of independent claim 1 which, for the reasons stated above, is believed to be patentably distinguishable over Clayton. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. § 103(a).

Rejection of Claims 12-20 and 22-23
Under 35 U.S.C. § 103(a) Over Clayton and Despotis

Claims 12-20 and 22-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of U.S. Patent No. 4,790,327 issued to Despotis

("Despotis"). In response, Applicants have amended claims 12 and 13 to more particularly point out and distinctly claim the subject matter of the invention.

With reference first to independent claim 12, this claim now recites that the connector proximal end has "an outer diameter of approximately 15 mm for receiving a standard breathing tube over the connector proximal end, the breathing tube remaining external to the patient" (*see* p. 4, lines 10-12; p. 7, lines 23-30; p. 8, lines 27-29). Applicants assert that Clayton does not disclose or suggest that her pacifier has the specific sizing necessary to compatibly attach to a standard breathing tube which remains external to the patient as in Applicants' claimed invention.

As is known to those skilled in the art, breathing tubes are required to have standard U.S. and international dimensions. In the United States, the dimension of 15 mm for breathing tubes is mandated by the Food and Drug Administration under ASTM Standard F1054-87. As such, the proximal end of Applicants' connector is specifically sized for secure connection with a standard breathing tube, such that an external anesthesia breathing circuit can be quickly and easily attached to the pacifier with a tight seal to prevent anesthesia gas from escaping at the interface (*see* p. 8, lines 18-31).

In contrast to Applicants' invention, Clayton is directed to a pacifier used to aid introduction of a feeding or medication tube into the oral cavity of a patient for administering fluids. Clayton discloses that her pacifier may be used with a gavage tube feeding system, wherein the gavage tube is threaded through the lumen 18 of the pacifier tube member 33, into the oral cavity, and subsequently down into the patient's esophagus to the stomach. Clayton does not disclose or suggest that tube member 33 has the specific 15 mm sizing necessary for secure connection to a breathing tube remaining external to the patient as in Applicants' claimed invention. Rather, Clayton states:

> "Tube member lumen 18 is a small diameter, hollow lumen, which is capable of removably receiving a small diameter tube or the like. In a preferred embodiment, the lumen is sized to

> receive a gavage feeding tube, and more preferably a number 5 or a number 8 gavage tube."
>
> (*see Clayton*, col. 4, lines 29-34)

Number 5 (i.e., 5 French) and number 8 (i.e., 8 French) size tubes translate to metric diameters of 1.67 mm and 2.7 mm, respectively. Clearly, the outer diameter of Clayton's tube member 33 need only be of sufficient diameter to accommodate tubes having diameters on the order of 2-3 mm. There is no reason to believe that a diameter of tube member 33 five times larger than that disclosed, as would be required for a secure connection to a standard breathing tube, would ever be necessary or contemplated in the scope of Clayton's invention.

The Examiner admits that Clayton fails to specifically teach the 15 mm connector dimension disclosed and claimed by Applicants, but asserts that Clayton instead teaches receiving a medication tube, where "a breathing tube constitutes a medication tube" (Office Action, Page 7, ¶15). Applicants respectfully disagree with this characterization. Clayton states that:

> "In operation, as shown in FIG. 4, pacifier assembly 10 may be used with a gavage feeding system, which includes a gavage tube 30 and a gavage container 60. Container 60 may be filled with a nutritive fluid, such as formula or breast milk. Optionally, tube 30 may be connected to a reservoir 60 containing medicine, or the like, or a viscous solution including charcoal, barium, vitamins, and lipids."
>
> (*see Clayton*, col. 4, line 66 - col. 5, line 5).

Clearly, the medication tube disclosed by Clayton is not synonymous with a standard breathing tube which remains external to the patient as is known to those skilled in the art. Clayton does not disclose or suggest the administration of medicine in any other form than that described above, and certainly does not disclose or suggest delivery of gas via the medication tube.

Furthermore, Clayton's disclosed method of providing medication is the same as that for feeding, namely threading one end of the tube through the pacifier and down the patient's throat (*see Clayton*, col. 3, lines 33-42), wherein the other end of the tube is connected to a reservoir containing liquid medication. This is in direct contrast to Applicants' claimed invention, since breathing tubes are never introduced into the patient's throat, but instead remain external to the patient as disclosed and claimed by Applicants. Likewise, Clayton's invention would not function properly if the feeding/medication tube remained external to the patient, as this configuration would not allow food or medicine to be introduced directly into the stomach.

The Examiner asserts that it would have been obvious to combine Clayton and Despotis and make Clayton's tube member a standard size (i.e., 15 mm) to allow connection to a standard breathing tube (Office Action, Page 7, ¶15). Applicants respectfully disagree, and assert that there is no motivation or suggestion to combine the Clayton and Despotis references. Clayton is directed only to providing liquid food or medication to a patient via a tube threaded through the pacifier and down the patient's throat, and does not disclose or suggest providing gas to a patient. Furthermore, Clayton teaches away from Applicants' claimed invention, disclosing only a feeding/medication tube that is inserted through the pacifier and down the patient's throat to deliver liquid to the stomach, with no teaching or suggestion of a breathing tube connecting externally to the patient over the connector proximal end for the delivery of gas to the patient. Lastly, Clayton does not recognize the problem solved by Applicants' invention, namely providing a pacifier having a connector specifically sized to be securely connected to a standard external breathing tube external to the patient for delivering gases to a patient. Applicants have explained that a specific pacifier construction is required for suitable connection to a standard breathing tube and circuit external to the patient, and Clayton clearly fails to realize the necessity of a tube member 33 sized to fulfill this requirement.

Accordingly, Applicants believe that claim 12 is patentably distinguishable over Clayton in view of Despotis, and reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

Turning now to independent claim 13, Applicants recite the combination of a breathing circuit and a medical pacifier connected to the breathing circuit, where the pacifier includes an inlet opening adapted to be connected to the inlet tube (i.e., standard breathing tube) of the breathing circuit, and where the inlet tube remains external to the patient. For the reasons stated above, Applicants assert that Clayton provides no disclosure or suggestion that her pacifier tube member is specifically sized for connection to a standard breathing tube remaining external to the patient.

The Examiner admits that Clayton fails to specifically teach a breathing circuit and an inlet tube (Office Action, p. 8, ¶16). However, the Examiner asserts that Clayton does disclose the use of the pacifier to administer medications through the tube, and that it would be obvious to provide a breathing circuit as a form of administering medicament to the patient (Office Action, Page 8, ¶16). Again, Applicants respectfully disagree. For the reasons stated above with reference to claim 12, Applicants assert that Clayton only discloses providing medication in fluid form using a gavage feeding tube which is necessarily inserted into the patient. There is no teaching or suggestion in Clayton to provide gases to the patient or to attach her pacifier to a breathing circuit having an inlet tube which remains external to the patient, nor is her pacifier configured to even be capable of attachment to such an inlet tube.

Therefore, claim 13 is believed to be patentably distinguishable over the combination of Clayton and Despotis, and Applicants respectfully request reconsideration and withdrawal of the rejection of this claim, and corresponding dependent claims 14-20 and 22-23, under 35 U.S.C. § 103(a).

Rejection of Claim 8
Under 35 U.S.C. § 103(a) Over Clayton and Stevens

Claim 8 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of U.S. Patent No. 5,810,000 issued to Stevens ("Stevens"). Claim 8 depends from and contains all the limitations of independent claim 1 which, for the reasons stated above, is believed to be patentably distinguishable over Clayton, either alone or in combination with Stevens. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 8 under 35 U.S.C. § 103(a).

Rejection of Claim 21
Under 35 U.S.C. § 103(a) Over Clayton, Despotis, and Stevens

Claim 21 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of Despotis and Stevens. Claim 21 depends from and contains all the limitations of independent claim 12 which, for the reasons stated above, is believed to be patentably distinguishable over Clayton and Despotis, either alone or in combination with Stevens. Therefore, Applicants also respectfully request reconsideration and withdrawal of this rejection.

Conclusion

In summary, Applicants believe that the claims, as amended, now meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

Respectfully submitted,

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Attachment: Replacement Sheet